REMARKS

Applicants have carefully reviewed the Final Office Action mailed on May 16, 2007. Currently claims 1-19 are pending in the application, wherein claims 1-19 have been rejected. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections Under 35 U.S.C. §102

Claims 1-19 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lenker et al., EP 0 696 447 A2. Applicants respectfully traverse this rejection.

Claim 1 recites:

> A self-expanding stent delivery assembly comprising:
> a shaft having a distal region and a longitudinal axis;
> a retractable sheath having a proximal end and a distal end, the retractable co-axially disposed around at least the shaft distal region;
> a stent disposed co-axially between the shaft and the retractable sheath in the distal region;
> a stop member coupled to the shaft and positioned proximally of the stent; and
> a tubular tapered tip affixed to the retractable sheath distal end, the tubular tapered tip having an elongate region predisposed to fracturing.

Applicants assert that in order to anticipate, the prior art must teach the claimed invention in as much detail, including all structural limitations, as provided in the claim. See *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989); *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Thus, the part-to-part relationship of components must be considered when evaluating claims. See *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Applicants assert that Lenker et al. do not teach each and every structural limitation of the claimed invention.

In formulating the rejection, it appears as though the Examiner is relying on Figures 1-5 and 31 of Lenker et al. The Examiner is equating the plurality of penetrating stay members 50 of Lenker et al. with the claimed stop.

Applicants respectfully note that as currently claimed the assembly includes the stent disposed co-axially between the shaft and the retractable sheath and the stop positioned proximally of the stent. Lenker et al. do not seem to teach this arrangement as currently claimed.

As shown in Figure 3 of Lenker et al., with the stent located between the shaft 34 and the sheath 32, the plurality of penetrating stay members 50 are located distal of the proximal end of

the stent P. The location of the penetrating stay members 50 allows the stay members 50 to extend through openings of the stent 50. Thus, some portion of the stent P must be located proximally of the stay members 50. Shown positioned between adjacent coils of the stent P, "the penetrating stays 50 will be able to anchor the proximal end of the tubular prosthesis P when it is held within the catheter." Lenker et al., at column 13, lines 21-24. Thus, as the penetrating stay members 50 are located distal of the proximal end of the stent P, the penetrating stay members 50 cannot be said to be positioned proximally of the stent, as currently claimed.

Furthermore, the Examiner appears to be relying on Figure 31 of Lenker et al. as disclosing a tubular tapered tip having an elongate region predisposed to fracturing, as currently claimed. Applicants assert that Lenker et al. do not teach these structural features at Figure 31. Figure 31 is reproduced below.

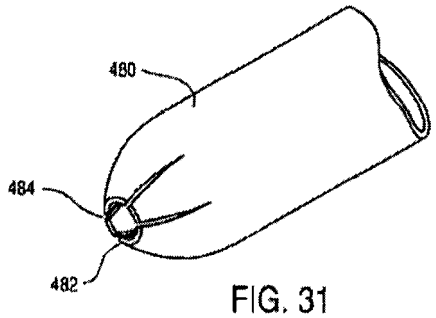

FIG. 31

Regarding Figure 31, Lenker et al. state:

> Referring now to Fig. 31, an alternative cover 480 provides an atraumatic distal end 482 with a reduced nosecone diameter, or, alternatively, no nosecone at the distal end of core shaft 444. Atraumatic cover 480 includes a series of splits 484 to allow the distal tip of atraumatic cover 480 to open during deployment of prosthesis 10.

Lenker et al. at column 21, lines 28-34 (emphasis added). Thus, the cover 480 includes a plurality of slits 484 cut through the cover 480.

Applicants assert that the slits or cuts 484 of the cover 480 of Lenker et al. are not equivalent to the "elongate region predisposed to fracturing" as currently claimed. The claimed "elongate region predisposed to fracturing" describes a region of the claimed tapered tip which is susceptible to being broken or separated, yet is not broken or separated prior to deployment of the stent. Applicants note that the present description describes three possible regions predisposed to fracturing at lines 3-8 of page 8. These three examples of an elongate region predisposed to fracturing are also claimed in claims 3 through 5. The present description states:

> In an illustrative embodiment, the elongate region predisposed to fracturing 90 can be a line of perforations that extend through a portion of or through the entire tubular tip 36 wall thickness. The elongate region predisposed to fracturing 90 can be a score line that extends through a portion of the tubular tip 36 wall thickness where the wall thickness along the score line 90 is less than the thickness along the remaining tubular tip 36 wall. Alternatively or in addition, the elongate region predisposed to fracturing 90 can be material having a tensile strength that is less than the tensile strength of the remaining tubular tip 36.

Thus, it can be seen that the claimed elongate region predisposed to fracturing is a region of material which holds adjacent portions of the tip together prior to being fractured, yet is a region which is susceptible to being broken to separate adjacent portions of the tip at a determined time.

To the contrary, the slits 484 cut through the cover 480 are not predisposed to fracturing as the slits 484 indicate that the portions of the cover 480 are already separated by the slits 484 and no further fracturing of the slits 484 is contemplated. The slits 484 are an absence of material, not a region of material which holds adjacent portions of the cover together prior to being fractured.

For at least these reasons, Lenker et al. do not anticipate claim 1. Claim 1 is believed patentable over the teachings of Lenker and withdrawal of the rejection is respectfully requested.

Claims 2-10 depend from claim 1 and include additional limitations not taught in Lenker et al. Therefore, these claims are also believed patentable over the teachings of Lenker et al. and withdrawal of the rejection is respectfully requested.

Applicants note that the Final Office Action includes no explanation as to where Lenker et al. teach the limitations claimed in claims 2-10. For example, there is no explanation as to where Lenker et al. teach an elongate region predisposed to fracturing is a line of perforations as claimed in claim 2, or where Lenker et al. teach an elongate region predisposed to fracturing which has a thickness less than the thickness of the tubular tip as claimed in claim 3, or where Lenker et al. teach an elongate region predisposed to fracturing which is formed of a material having a tensile strength less than the tensile strength of the material forming the tubular tip as claimed in claim 4.

Applicants note that the Examiner has an obligation to clearly state the grounds for rejecting each of the claims in every Office Action. See M.P.E.P. §707.07(d). If the Examiner wishes to renew the rejection of these claims, Applicants respectfully request the Examiner

clearly indicate what portion of Lenker et al. is relied upon in formulating the rejection, such that the Applicants are afforded an opportunity to properly respond. See M.P.E.P. §707.07(f).

Claim 11 recites:

> A method of delivering a self-expanding stent comprising:
> placing a stent delivery device at a target site, the stent delivery device comprising:
> a shaft having a distal region and a longitudinal axis;
> a retractable sheath having a proximal end and a distal end, the retractable sheath co-axially disposed around the shaft distal region;
> a stent disposed co-axially between the shaft and the retractable sheath in the distal region;
> a stop member coupled to the shaft and positioned proximally of the stent; and
> a tubular tapered tip affixed to the retractable sheath distal end, the tubular tapered tip having an elongate region predisposed to fracturing;
> deploying the stent at the target site by retracting the retractable sheath or advancing the stent and fracturing the elongate region predisposed to fracturing; and
> removing the stent delivery device from the target site.

The remarks above regarding the allowabiltiy of claim 1 are renewed with regard to Claim 11. Furthermore Applicants assert Lenker et al. do not teach the limitation of the method of claim 11 of "fracturing the elongate region predisposed to fracturing." There is no discussion in Lenker et al. of fracturing the slits 484 of the cover 480 which would meet the limitations of claim 11.

For at least the reasons stated above, claim 11 is believed patentable over Lenker et al. Withdrawal of the rejection is respectfully requested. Claims 12-19, which depend from claim 11 and add significant additional limitations, are also believed patentable over Lenker et al. Similar to Applicants' indication above regarding claims 2-10, Applicants note that the Office Action includes no explanation as to where Lenker et al. teach the limitations claimed in claims 12-19. If the Examiner wishes to renew the rejection of these claims, Applicants respectfully request the Examiner clearly indicate what portion of Lenker et al. is relied upon in formulating the rejection, such that the Applicants are afforded an opportunity to properly respond. See M.P.E.P. §707.07(f).

Conclusion

Reexamination and reconsideration are requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is also respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

Date: 7/18/07

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